September 22, 1999

The Honorable Jane Henney, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

The undersigned support the petition filed by the Center for Science in the Public Interest (CSPI) asking the Food and Drug Administration to require that explicit label notices be included on products containing one gram or more of sorbitol per serving.

Having studied the adverse effects of sorbitol on the gastrointestinal systems of both adults and children, we are especially concerned about the lack of public awareness surrounding the numerous "sugar-free" foods, gums, and other products that contain sorbitol and related sugar alcohols. In clinical trials and in the general public, sugar alcohols have resulted in serious diarrhea and other symptoms. While the FDA has required labeling of a small subset of sorbitol-containing products since 1973, we believe the regulation is not stringent enough to protect the public's health. The current regulation falls short in a number of ways:

1. The current regulation does not take into account subsequent clinical studies that demonstrate the ill effects of sorbitol. Under current regulations, only foods likely to provide 50 grams or more of sorbitol per day are required to bear a notice label. That threshold is far too high. Clinical studies performed by us and other researchers have shown that adults may experience diarrhea and other gastrointestinal problems after consuming as little as 10 grams of sorbitol per day. The current regulation must be revised to take those new clinical findings into account. Furthermore, since sorbitol is present in many food products and medicines today, daily consumption might regularly exceed 10 grams per day, including sorbitol from a variety of sources rather than from a single product. The current regulation does not incorporate that consideration.

2. The current labeling notice is too vague, and does not address children's particular susceptibility to sorbitol. The current labeling notice required by the FDA warns that "excess consumption [of the product] may have a laxative effect." That statement trivializes the potential for extreme gastrointestinal distress, does not clearly indicate what constitutes "excess consumption," and does not point out that children may be affected by relatively small amounts of sorbitol. The notice label should read, as CSPI suggests, "NOTICE: This product contains sorbitol, which may cause diarrhea, bloating, and abdominal pain. Not suitable for consumption by children. To protect yourself, start by eating no more than one serving at a time."

While CSPI's petition focuses primarily on the labeling requirements for products containing sorbitol, the same considerations apply to products containing other sugar alcohols, such as mannitol, maltitol, isomalt, xylitol, and hydrogenated starch hydrolysate. Those

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substances also may cause diarrhea and other gastrointestinal problems, particularly in children and other susceptible individuals.

Better labeling of sugar alcohols is particularly important considering that FDA regulations allow labels to declare the health benefits (lack of cariogenicity) of foods containing those substances, and to emphasize that the products are "sugar free" and often "low calorie." FDA should take action to ensure that consumers also are fully informed about the adverse effects associated with the sugar alcohols.

Thank you for your prompt attention to this public health matter. (Please respond to the cosigners by writing to the Center for Science in the Public Interest).

Sincerely,

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